

KKB/SAS:hmm 04/08/09 declaration from Dr Marino for Bauman.doc 02-095 Attorney Reference Number 6915-66816-01
Application Number 10/672,241

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Korsten and Bauman

Application No. 10/672,241

Filed: September 25, 2003

Confirmation No. 8718

For: COMPOSITIONS AND METHODS FOR
BOWEL CARE IN INDIVIDUALS WITH
CHRONIC INTESTINAL PSEUDO-
OBSTRUCTION

FILED VIA EFS

Examiner: Jennifer M. Kim

Art Unit: 1614

Attorney Reference No. 6915-66816-01

FILED VIA EFS
COMMISSIONER FOR PATENTS

DECLARATION OF DR. MARINO UNDER 37 CFR § 1.132

1. I, Dr. Ralph Marino, am a full-time academic physician at Thomas Jefferson Hospital, Philadelphia, Pennsylvania. I specialize in treating patients with spinal cord injuries and have been practicing in the field of rehabilitation medicine since 1988.

2. As a practicing physician, I did not consider neostigmine with or without glycopyrrolate to be an effective treatment of chronic constipation. Specifically, there are known risks associated with providing anticholinergic agents to subjects with spinal cord injuries as well as a need to constantly monitor the subject during such drug administration. It's my understanding that the use of neostigmine and glycopyrrolate to treat chronic intestinal pseudo-obstruction to alleviate chronic constipation was first disclosed as a treatment modality in the above-referenced patent application.

3. To my knowledge, the clinical practice guidelines for treating chronic constipation to date do not include administration of neostigmine with or without glycopyrrolate. Instead, as noted in the references provided in Appendix A chronic constipation is treated by non-pharmacological approaches (such as increasing fiber in diet, increasing physical activity, or

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cognitive behavior therapy) as well as pharmacological approaches (such as polyethylene glycol and stimulant laxatives). (See Consortium for Spinal Cord Medicine, *Neurogenic Bowel Management in Adults with Spinal Cord Injury*, PVA, 1998; Foxx-Orenstein *et al.*, *Cleveland Clinic Journal of Medicine* 75(11): 813-824, 2008; Gallagher *et al.*, *Drugs Aging* 25(10): 807-821, 2008; Pohl *et al.*, *Current Opinion in Pharmacology* 8: 724-728, 2008; and Singal *et al.*, *Advances in Medical Sciences* 51: 15-22, 2006).

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Executed at the place and date opposite the signature below.

At Philadelphia, PA
(City and State)
on this 8th day of April, 2009.

Ralph Marino
Ralph Marino